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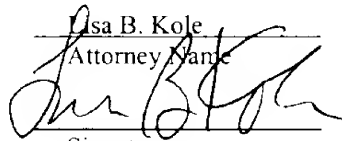
Applicant : Fisher *et al.*
Serial No. : 09/515,363 Examiner : Qian, C.
Filed : February 29, 2000 Group Art Unit: 1636
For : MELANOMA DIFFERENTIATION ASSOCIATED GENE-
5 AND PROMOTER AND USES THEREOF

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

September 22, 2003

Date of Deposit

Isa B. Kole
Attorney Name
Signature35,225

PTO Registration No.

September 22, 2003

Date of Signature

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In supplement to the Information Disclosure Statement filed on November 14, 2000, and pursuant to the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants respectfully request that the publications relating to the above-mentioned application

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listed herein and on the accompanying PTO Form 1449 be considered by the Examiner and made of record in the U.S. Patent and Trademark Office.

The publications contained herein, listed in reverse chronological order, are identified as numbers 16 through 99, to distinguish them from the 15 publications previously disclosed in the above-identified application. These documents were cited in the specification of the above-identified application, and in the International Search Report issued by the United States Patent Office for International Patent Application PCT/US01/06960, which claims priority to the instant application. A copy of this search report also is enclosed. The citations listed below are also listed in the accompanying PTO Form 1449.

16. Kang DC, Gopalkrishnan RV, Jiang H, Wu Q, Fisher PB (2000). Melanoma differentiation associated gene 5 (MDA-5): A novel interferon-inducible putative RNA helicase involved in cell survival. *Proceedings of the American Association for Cancer Research* 41:509-510 (Abstract #3250).
17. United States Patent No. 6,051,376 (Fisher *et al.*), issued April 18, 2000, entitled "Uses of mda-6."
18. United States Patent No. 6,025,127 (Sidransky), issued February 15, 2000, entitled "Nucleic acid mutation detection in histologic tissue."
19. United States Patent No. 5,912,236 (Xu *et al.*), issued June 15, 1999, entitled "Broad-spectrum tumor suppressor genes gene products and methods for tumor suppressor gene therapy."

20. Bult CJ (1998). Putative ATP-dependent RNA helicase MJ1505. SwissProt Acc. No. Q58900.
21. United States Patent No. 5,643,761 (Fisher *et al.*), issued July 1, 1997, entitled "Method for generating a subtracted cDNA library and uses of the generated library."
22. Wood V *et al.* (1996). Putative helicase C188.13c. SwissProt Acc. No. Q09884
23. International Patent Application No. PCT/US94/12160 by Fisher *et al.* entitled "Method for generating a subtracted cDNA library and uses of the generated library," published as WO95/11986 on May 4, 1995.
24. United States Patent No. 5,399,346 (Anderson *et al.*), issued March 21, 1995, entitled "Gene Therapy."
25. Algate PA, Steelman LS, Mayo MW, Miyajima A, McCubrey JA (1994). Regulation of the interleukin-3 (IL-3) receptor by IL-3 in the fetal liver-derived FL5.12 cell line. *Blood* 83:2459-2468.
26. Cluitmans FH, Esendam BH, Landegent JE, Willemze R, Falkenburg JH (1994). IL-4 down-regulates IL-2, IL-3-, and GM-CSF-induced cytokine gene expression in peripheral blood monocytes. *Ann. Hematol.* 68:293-298.
27. de Wit H, Esselink MT, Halie MR, Vellenga E (1994). Differential regulation of M-CSF and IL-6 gene expression in monocytic cells. *Br. J. Haematol.* 86:259-264.

28. Jiang H, Lin J, Fisher PB (1994). A molecular definition of terminal differentiation in human melanoma cells. *Mol. Cell. Different.* 2:221-239.
29. Lagoo AS, Lagoo-Deenadayalan S, Lorenz HM, Byrne J, Barber WH, Hardy KJ (1994). IL-2, IL-4, and IFN-gamma gene expression versus secretion in superantigen-activated T cells. Distinct requirement for costimulatory signals through adhesion molecules. *J. Immunol.* 152:1641-1652.
30. Pang G, Couch L, Batey R, Clancy R, Cripps A (1994). GM-CSF, IL-1 alpha, IL-1 beta, IL-6, IL-8, IL-10, ICAM-1 and VCAM-1 gene expression and cytokine production in human duodenal fibroblasts stimulated with lipopolysaccharide, IL-1 alpha and TNF-alpha. *Clin. Exp. Immunol.* 96:437-443.
31. Shimane M, Tani K, Maruyama K, Takahashi S, Ozawa K, Asano S (1994). Molecular cloning and characterization of G-CSF induced gene cDNA. *Biochem. Biophys. Res. Commun.* 199:26-32.
32. Wilson R *et al.* (1994). Endoribonuclease dcr-1. SwissProt Acc. No. P34529.
33. International Patent Application No. PCT/US93/04454 by Myers *et al.* entitled "Use of inhibitors of 3-hydroxy-3-methylglutaryl coenzyme A reductase as a modality in cancer therapy", published as WO 93/23034 on 25 November 1993.
34. Martinez OM, Villanueva JC, Lake J, Roberts JP, Ascher NL, Krams SM (1993). IL-2 and IL-5 gene expression in response to alloantigen in liver allograft recipients 10 and in vitro. *Transplantation* 55:1159-1166.

35. Pizarro TT, Malinowska K, Kovacs EJ, Clancy J Jr, Robinson JA, Piccinini LA (1993). Induction of TNF alpha and TNF beta gene expression in rat cardiac transplants during allograft rejection. *Transplantation* 56:399-404.
36. Anderson WF (1992). The June RAC meeting. *Hum. Gene Ther.* 3:459-460.
37. Berkner KL (1992). Expression of heterologous sequences in adenoviral vectors. *Curr. Top. Microbiol. Immunol.* 158:39-66.
38. Breviario F, d'Aniello EM, Golay J, Peri G, Bottazzi B, Bairoch A, Saccone S, Marzella R, Predazzi V, Rocchi M, et al. (1992). Interleukin-1-inducible genes in endothelial cells. Cloning of a new gene related to C-reactive protein and serum amyloid P component. *J. Biol. Chem.* 267:22190-22197.
39. Espinoza-Delgado I, Longo DL, Gusella GL, Varesio L (1992). Regulation of IL-2 receptor subunit genes in human monocytes. Differential effects of IL-2 and IFN-gamma. *J. Immunol.* 149:2961-2968.
40. Li YP, Stashenko P (1992). Proinflammatory cytokines tumor necrosis factor-alpha and IL-6, but not IL-1, down-regulate the osteocalcin gene promoter. *J. Immunol.* 148:788-794.
41. Mauviel A, Reitamo S, Remitz A, Lapiere JC, Ceska M, Baggiolini M, Walz A, Evans CH, Uitto J (1992). Leukoregulin, a T cell-derived cytokine, induces IL-8 gene expression and secretion in human skin fibroblasts. Demonstration and secretion in human skin fibroblasts. Demonstration of enhanced NF-kappa B binding and NF-kappa B-driven promoter activity. *J. Immunol.* 149:2969-2976.

42. Sprecher E, Becker Y (1992). Detection of IL-1 beta, TNF-alpha, and IL-6 gene transcription by the polymerase chain reaction in keratinocytes, Langerhans cells and peritoneal exudate cells during infection with herpes simplex virus-1. Arch. Virol. 126:253-269.
43. Canonico AE, Conary JT, Christman BW, Meyrick BO, Brigham KL (1991). Expression of a CMV promoter driven human α -1 antitrypsin gene in cultured lung endothelial cells and in the lungs of rabbits. Clin. Res. 39:219A (abstract).
44. Culver KW, Anderson WF, Blaese RM (1991). Lymphocyte gene therapy. Hum. Gene Ther. 2:107-109.
45. Hazinski TA, Ladd PA, DeMatteo CA (1991). Localization and induced expression of fusion genes in the rat lung. Am. J. Respir. Cell Mol. Biol. 4:206-209.
46. Kay AB, Ying S, Varney V, Gaga M, Durham SR, Moqbel R, Wardlaw AJ, Hamid Q (1991). Messenger RNA expression of the cytokine gene cluster, interleukin 3 (IL-3), IL-4, IL-5, and granulocyte/macrophage colony-stimulating factor, in allergen-induced late-phase cutaneous reactions in atopic subjects. J. Exp. Med. 173:775-778.
47. Rosenfeld MA, Siegfried W, Yoshimura K, Yoneyama K, Fukayama M, Stier LE, Paakko PK, Gilardi P, Stratford-Perricaudet LD, Perricaudet M, *et al.* (1991). Adenovirus-mediated transfer of a recombinant alpha 1-antitrypsin gene to the lung epithelium in vivo. Science 252:431-434.

48. Ulich TR, Guo KZ, Remick D, del Castillo J, Yin SM (1991). Endotoxin-induced cytokine gene expression in vivo. III. IL-6 mRNA and serum protein expression and the in vivo hematologic effects of IL-6. *J. Immunol.* 146:2316-2323.
49. Fisher PB, Rowley PT (1991). Regulation of growth, differentiation, and antigen expression in human tumor cells by recombinant cytokines: applications for the differentiation therapy of human cancer. In: Waxman S, Rossi GB, Takaku F, Eds. *The Status of Differentiation Therapy of Cancer, Vol. 2. Serono Symposia Pubs.*, Raven Press, New York, pp. 201-214.
50. Anderson WF, Blaese RM, Culver K (1990). The ADA human gene therapy clinical protocol: Points to Consider response with clinical protocol, July 6, 1990. *Hum. Gene Ther.* 1:331-362.
51. Geller AI, Keyomarsi K, Bryan J, Pardee AB (1990). An efficient deletion mutant packaging system for a defective herpes simplex virus vectors: potential applications to human gene therapy and neuronal physiology. *Proc. Natl. Acad. Sci. USA* 87:8950-8954.
52. Horisberger MA, McMaster GK, Zeller H, Wathelet MG, Dellis J, Content J (1990). Cloning and sequence analyses of cDNAs for interferon-beta and virus-induced human Mx proteins reveal that they contain putative guanine nucleotide-binding sites: functional study of the corresponding gene promoter. *J. Virol.* 64:1171-1181.
53. International Patent Application No. PCT/US90/01515 by Felgner *et al.* entitled "Expression of exogenous polynucleotide sequences in a vertebrate," published as WO 90/11092 on 4 October 1990.

54. Kaufman RJ (1990). Vectors used for expression in mammalian cells. *Meth. Enzymol.* 185:487-511.
55. Nabel EG, Plautz G, Nabel GJ (1990). Site-specific gene expression in vivo by direct gene transfer into the arterial wall. *Science* 249:1285-1288.
56. Wolff JA, Malone RW, Williams P, Chong W, Acsadi G, Jani A, Felgner PL (1990). Direct gene transfer into mouse muscle in vivo. *Science* 247:1465-1468.
57. Brigham KL, Meyrick B, Christman B, Magnuson M, King G, Berry LC Jr (1989). In vivo transfection of murine lungs with a functioning prokaryotic gene using a liposome vehicle. *Am. J. Med. Sci.* 298:278-281.
58. Felgner PL, Holm M (1989). Cationic-liposome mediated transfection. *Focus* 11:21-25.
59. Felgner PL, Holm M, Chan H (1989). Cationic liposome mediated transfection. *Proc. West. Pharmacol. Soc.* 32: 115-121.
60. Berkner KL (1988). Development of adenovirus vectors for the expression of heterologous genes. *BioTechniques* 6:616-629.
61. DePamphilis ML, Herman SA, Martinez-Salas E, Chalifour LE, Wirak DO, Cupo DY, Miranda M (1988). Microinjecting DNA into mouse ova to study DNA replication and gene expression and to produce transgenic animals. *BioTechniques* 6:662-680.

62. Guild BC, Finer MH, Housman DE, Mulligan RC (1988). Development of retrovirus vectors useful for expressing genes in cultured murine embryonic cells and hematopoietic cells in vivo. *J Virol.* 62:3795-3801.
63. McGrory WJ, Bautista DS, Graham FL (1988). A simple technique for the rescue of early region I mutations into infectious human adenovirus type 5. *Virology* 163(2):614-617.
64. Waxman, S., G.B. Rossi, and T. F., The Status of Differentiation Therapy of Cancer, in The Status of Differentiation Therapy of Cancer, S. Waxman, G.B. Rossi, and T. F., Editors. 1988, Raven Press: New York, NY. P. 1-422 (**Table of Contents only**).
65. Felgner PL, Gadek TR, Holm M, Roman R, Chan HW, Wenz M, Northrop JP, Ringold GM, Danielsen M (1987). Lipofection: a highly efficient, lipid-mediated DNA-transfection procedure. *Proc. Natl. Acad. Sci. USA* 84:7413-7417.
66. Ghosh-Choudhury G, Graham FL (1987). Stable transfer of a mouse dihydrofolate reductase gene into a deficient cell line using human adenovirus vector. *Biochem. Biophys. Res. Commun.* 147(3):964-973.
67. Rossi P, de Crombrughe B (1987). Identification of a cell-specific transcriptional enhancer in the first intron of the mouse alpha 2 (type I) collagen gene. *Proc. Natl. Acad. Sci. USA* 84:5590-5594.

68. Ghosh-Choudhury G, Haj-Ahmad Y, Brinkley P, Rudy J, Graham FL (1986). Human adenovirus cloning vectors based on infectious bacterial plasmids. *Gene* 50:161-171.
69. Haj-Ahmad Y, Graham FL (1986). Development of a helper-independent human adenovirus vector and its use in the transfer of the herpes simplex virus thymidine kinase gene. *J. Virol.* 57:257-274.
70. Hock RA, Miller AD (1986). Retrovirus mediated transfer and expression of drug resistance genes in human hemopoietic progenitor cells. *Nature* 320:275-277.
71. Stavridis JC, Deliconstantinos G, Psallidopoulos MC, Armenakas NA, Hadjiminis DJ, Hadjiminis J (1986). Construction of trans ferrin-coated liposomes for in vivo transport of exogenous DNA to bone marrow erythroblasts in rabbits. *Exp. Cell Res.* 164:568-572.
72. Wigand R, Adrian T (1986). Classification and epidemiology of adenoviruses. In: *Adenovirus DNA*. Doerfler W, ed. Martinus Nijhoff Pub., Boston. pp. 408-441.
73. Fisher PB, Prignoli DR, Herms H Jr, Weinstein IB, Pestka S (1985). Effects of combined treatment with interferon and mezerein on melanogenesis and growth in human melanoma cells. *J. Interferon Res.* 5:11-22.
74. Kaufman RJ (1985). Identification of the component necessary for adenovirus translational control and their utilization in cDNA expression vectors. *Proc. Natl. Acad. Sci. USA* 82:689-693.

75. Schmidt A, Setoyama C, de Crombrughe B (1985). Regulation of a collagen gene promoter by the product of viral mos oncogene. *Nature* 314:286-289.
76. Wong GG, Witek JS, Temple PA, Wilkens KM, Leary AC, Luxenberg DP, Jones SS, Brown EL, Kay RM, Orr EC, Shoemaker C, Golde DW, Kaufman RJ, Hewick RM, Wang EA, Clark SC (1985). Human GM-CSF: Molecular cloning of the complementary DNA and purification of the natural and recombinant proteins. *Science* 228:810-815.
77. Van Doren K, Gluzman Y (1984). Efficient transformation of human fibroblasts by adenovirus-simian virus 40 recombinants. *Mol. Cell. Biol.* 4(8):1653-1656.
78. Berkner KL, Sharp PA (1983). Generation of adenovirus by transfection of plasmids. *Nucleic Acids Res.* 11(17):6003-6020.
79. Capecchi MR, Luciw PA, Bishop JM, Varmus HE (1983). Location and function of retroviral and SV40 sequences that enhance biochemical transformation after microinjection of DNA. In: *Enhancer and Eukaryotic Gene Expression*. Gluzman Y, Shenk T, eds. Cold Spring Harbor Laboratories. pp. 101-102.
80. Jolly DJ, Esty AC, Subramani S, Friedmann T, Verma IM (1983). Elements in the long terminal repeat of murine retroviruses enhance stable transformation by thymidine kinase gene. *Nucleic Acids Res.* 11:1855-1872.
81. Panicali D, Paoletti E (1983). Construction of poxvirus as cloning vectors: Insertion of the thymidine kinase gene from herpes simplex virus into the DNA of infectious vaccine virus. *Proc. Natl. Acad. Sci. USA* 79:4927-4931.

82. Smith GL, Mackett M, Moss B (1983). Infectious vaccinia virus recombinants that express hepatitis B virus surface antigens. *Nature* 302:490-495.
83. Gorman CM, Moffat LF, Howard BH (1982). Recombinant genomes which express chloramphenicol acetyltransferase in mammalian cells. *Mol. Cell. Biol.* 2(9):1044-1051.
84. Gluzman Y, Reichl H, Solnick D (1982). Helper-free adenovirus type-5 vectors. In: *Eukaryotic Viral Vectors*. Gluzman Y, ed. Cold Spring Harbor Laboratories. pp. 187-192.
85. Schaefer-Ridder M, Wang Y, Hofschneider PH (1982). Liposomes as gene carriers: Efficient transduction of mouse L cells by thymidine kinase gene. *Science* 215:166-168.
86. Breathnach R, Chambon P (1981). Organization and expression of eucaryotic split genes coding for proteins. *Ann. Rev. Biochem.* 50:349-383.
87. Colbere-Garapin F, Horodniceanu F, Kourilsky P, Garapin AC (1981) A new dominant hybrid selective marker for higher eukaryotic cells. *J. Mol. Biol.* 150:1-14.
88. Mulligan RC, Berg P (1981). Selection for animal cells that express the *Escherichia coli* gene coding for xanthine-guanine phosphoribosyltransferase. *Proc. Natl. Acad. Sci. USA* 78:2072-2076.

89. Ringold G, Dieckmann B, Lee F (1981). Co-expression and amplification of dihydrofolate reductase cDNA and the Escherichia coli XGPRT gene in Chinese hamster ovary cells. *J. Mol. Appl. Genet.* 1:165-175.
90. Sarver N, Gruss P, Law MF, Khoury G, Howley PM (1981). Bovine papilloma virus DNA: a novel eukaryotic cloning vector. *Mol. Cell Biol.* 1:486-496.
91. Corden J, Wasylyk B, Buchwalder A, Sassone-Corsi P, Keding C, Chambon P (1980). Promoter sequences of eukaryotic protein-coding genes. *Science* 209:1406-1414.
92. Maxam AM, Gilbert W (1980). Sequencing end-labeled DNA with base-specific chemical cleavages. *Methods Enzymol.* 65:499-560.
93. Urlaub G, Chasin LA (1980). Isolation of Chinese hamster cell mutants deficient in dihydrofolate reductase activity. *Proc. Natl. Acad. Sci. USA* 77:4216-4220.
94. Bacchetti S, Graham FL (1977). Transfer of gene for thymidine kinase-deficient human cells by purified herpes simplex viral DNA. *Proc. Natl. Acad. Sci. USA* 74:1590-1594.
95. Fowler AV, Zabin I (1977). The amino acid sequence of beta-galactosidase of Escherichia coli. *Proc. Natl. Acad. Sci. USA* 74(4):1507-1510.
96. Tu SC, Waters CA, Hastings JW (1975). Photoexcited bacterial bioluminescence. Identity and properties of the photoexcitable luciferase. *Biochemistry* 14(9):1970-1974.

97. Armelin HA (1973). Pituitary extracts and steroid hormones in the control of 3T3 cell growth. Proc. Natl. Acad. Sci. USA 70:2702-2706.
98. Graham FL, van der Eb AJ (1973). A new technique for the assay of infectivity of human adenovirus 5 DNA. Virology 52:456-467.
99. Freireich EJ, Gehan EA, Rall DP, Schmidt LH, Skipper HE (1966). Quantitative comparison of toxicity of anticancer agents in mouse, rat, hamster, dog, monkey, and man. Cancer Chemother. Rep. 50 :219-244.
100. Waxman, S. Ed., Differentiation Therapy (Ares Serono Symposia Publications, Rome) Vol 10, 1995 p 1-531 (TABLE OF CONTENTS ONLY).

Applicant would provide further material relating to reference 100, for which a Table of Contents is provided, upon the request of the Examiner.

In addition, please note that there were typographical errors in the dates specified previously for references 6, 7 and 12. Corrected versions of these citations are provided in the PTO 1449 form submitted herewith.

The submission of this Supplemental Information Disclosure Statement does not represent that a search has been made or that no better art exists, and does not constitute an admission that any of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Applicants believe a fee of \$180.00 is required under 37 C.F.R. § 1.17(p) for submission of this Supplemental Information Disclosure Statement after mailing of the first Office Action but before the mailing date of any final action, and accordingly enclose a check for \$180.00. If any other fee is required in connection with this communication or any overpayment has been made, please charge any deficiency or credit any overpayment to Deposit Account No. 02-4377. Two copies of this communication are enclosed.

Respectfully submitted,

BAKER BOTTS L.L.P.

A handwritten signature in cursive script, appearing to read 'Lisa B. Kole', written over a horizontal line.

Lisa B. Kole

Patent Office Reg. No. 35,225

Attorneys for Applicants

(212) 408-2500

Enclosures

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) SEP 26 2003 U.S. PATENT & TRADEMARK OFFICE	Atty. Docket No. A34614 (070050.1690)	Serial No. 09/515,363
	Applicant Fisher <i>et al.</i>	
	Filing Date February 29, 2000	Group 1636
	Examiner Qian, C.	

U.S. PATENT DOCUMENTS

*Exam. Init.	Document No.							Date	Name	Class	Subclass	Filing Date if Appro.
	17.	6	0	5	1	3	7	6	04/18/00	Fisher <i>et al.</i>		
	18.	6	0	2	5	1	2	7	02/15/00	Sidransky <i>et al.</i>		
	19.	5	9	1	2	2	3	6	06/15/99	Xu <i>et al.</i>		
	21.	5	6	4	3	7	6	1	07/01/97	Fisher <i>et al.</i>		
	24.	5	3	9	9	3	4	6	03/21/95	Anderson <i>et al.</i>		

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Subclass	Translation Yes No
23.	WO95/11986	05/04/95	WIPO			
33.	WO93/23034	11/25/93	WIPO			
53.	WO90/11092	10/04/90	WIPO			

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

16.	Kang DC, Gopalkrishnan RV, Jiang H, Wu Q, Fisher PB (2000). Melanoma differentiation associated gene 5 (MDA-5): A novel interferon-inducible putative RNA helicase involved in cell survival. Proceedings of the American Association for Cancer Research 41:509-510 (Abstract #3250).
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NY02:458771.1

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A34614 (070050.1690)	Serial No. 09/515,363
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22.	Wood V <i>et al.</i> (1996). Putative helicase C188.13c. SwissProt Acc. No. Q09884.
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34.	Martinez OM, Villanueva JC, Lake J, Roberts JP, Ascher NL, Krams SM (1993). IL-2 and IL-5 gene expression in response to alloantigen in liver allograft recipients 10 and in vitro. <i>Transplantation</i> 55:1159-1166.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	RECEIVED	
(Use several sheets if necessary)	OCT 02 2003	
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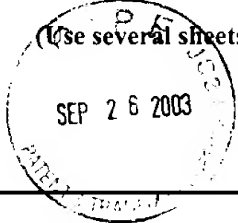
35.	Pizarro TT, Malinowska K, Kovacs EJ, Clancy J Jr, Robinson JA, Piccinini LA (1993). Induction of TNF alpha and TNF beta gene expression in rat cardiac transplants during allograft rejection. Transplantation 56:399-404.
36.	Anderson WF (1992). The June RAC meeting. Hum. Gene Ther. 3:459-460.
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40.	Li YP, Stashenko P (1992). Proinflammatory cytokines tumor necrosis factor-alpha and IL-6, but not IL-1, down-regulate the osteocalcin gene promoter. J. Immunol. 148:788-794.
41.	Mauviel A, Reitamo S, Remitz A, Lapiere JC, Ceska M, Baggolini M, Walz A, Evans CH, Uitto J (1992). Leukoregulin, a T cell-derived cytokine, induces IL-8 gene expression and secretion in human skin fibroblasts. Demonstration and secretion in human skin fibroblasts. Demonstration of enhanced NF-kappa B binding and NF-kappa B-driven promoter activity. J. Immunol. 149:2969-2976.
42.	Sprecher E, Becker Y (1992). Detection of IL-1 beta, TNF-alpha, and IL-6 gene transcription by the polymerase chain reaction in keratinocytes, Langerhans cells and peritoneal exudate cells during infection with herpes simplex virus-1. Arch. Virol. 126:253-269.
43.	Canonico AE, Conary JT, Christman BW, Meyrick BO, Brigham KL (1991). Expression of a CMV promoter driven human alpha-1 antitrypsin gene in cultured lung endothelial cells and in the lungs of rabbits. Clin. Res. 39:219A (abstract).
44.	Culver KW, Anderson WF, Blaese RM (1991). Lymphocyte gene therapy. Hum. Gene Ther. 2:107-109. Hazinski TA, Ladd PA, DeMatteo CA (1991). Localization and induced expression of fusion genes in the rat lung. Am. J. Respir. Cell Mol. Biol. 4:206-209.

NY02:458771.1

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A34614 (070050.1690)	Serial No. 09/515,363
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	Filing Date February 29, 2000	Group 1636 RECEIVED
	Examiner Qian, C.	OCT 02 2003
TECH CENTER 1600/2900		

45.	Hazinski TA, Ladd PA, DeMatteo CA (1991). Localization and induced expression of fusion genes in the rat lung. <i>Am. J. Respir. Cell Mol. Biol.</i> 4:206-209.
46.	Kay AB, Ying S, Varney V, Gaga M, Durham SR, Moqbel R, Wardlaw AJ, Hamid Q (1991). Messenger RNA expression of the cytokine gene cluster, interleukin 3 (IL-3), IL-4, IL-5, and granulocyte/macrophage colony-stimulating factor, in allergen-induced late-phase cutaneous reactions in atopic subjects. <i>J. Exp. Med.</i> 173:775-778.
47.	Rosenfeld MA, Siegfried W, Yoshimura K, Yoneyama K, Fukayama M, Stier LE, Paakko PK, Gilardi P, Stratford-Perricaudet LD, Perricaudet M, <i>et al.</i> (1991). Adenovirus-mediated transfer of a recombinant alpha 1-antitrypsin gene to the lung epithelium in vivo. <i>Science</i> 252:431-434.
48.	Ulich TR, Guo KZ, Remick D, del Castillo J, Yin SM (1991). Endotoxin-induced cytokine gene expression in vivo. III. IL-6 mRNA and serum protein expression and the in vivo hematologic effects of IL-6. <i>J. Immunol.</i> 146:2316-2323.
49.	Fisher PB, Rowley PT (1991). Regulation of growth, differentiation, and antigen expression in human tumor cells by recombinant cytokines: applications for the differentiation therapy of human cancer. In: Waxman S, Rossi GB, Takaku F, Eds. <i>The Status of Differentiation Therapy of Cancer, Vol. 2. Serono Symposia Pubs.</i> , Raven Press, New York, pp. 201-214.
50.	Anderson WF, Blaese RM, Culver K (1990). The ADA human gene therapy clinical protocol: Points to Consider response with clinical protocol, July 6, 1990. <i>Hum. Gene Ther.</i> 1:331-362.
51.	Geller AI, Keyomarsi K, Bryan J, Pardee AB (1990). An efficient deletion mutant packaging system for a defective herpes simplex virus vectors: potential applications to human gene therapy and neuronal physiology. <i>Proc. Natl. Acad. Sci. USA</i> 87:8950-8954.
52.	Horisberger MA, McMaster GK, Zeller H, Wathélet MG, Dellis J, Content J (1990). Cloning and sequence analyses of cDNAs for interferon-beta and virus-induced human Mx proteins reveal that they contain putative guanine nucleotide-binding sites: functional study of the corresponding gene promoter. <i>J. Virol.</i> 64:1171-1181.
54.	Kaufman RJ (1990). Vectors used for expression in mammalian cells. <i>Meth. Enzymol.</i> 185:487-511.
55.	Nabel EG, Plautz G, Nabel GJ (1990). Site-specific gene expression in vivo by direct gene transfer into the arterial wall. <i>Science</i> 249:1285-1288.

NY02:458771.1

Examiner

Date Considered

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	Filing Date February 29, 2000	Group 1636
	Examiner Qian, C.	

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OCT 02 2003
TECH CENTER 1600/2900

56.	Wolff JA, Malone RW, Williams P, Chong W, Acsadi G, Jani A, Felgner PL (1990). Direct gene transfer into mouse muscle in vivo. <i>Science</i> <u>247</u> :1465-1468.
57.	Brigham KL, Meyrick B, Christman B, Magnuson M, King G, Berry LC Jr (1989). In vivo transfection of murine lungs with a functioning prokaryotic gene using a liposome vehicle. <i>Am. J. Med. Sci.</i> <u>298</u> :278-281.
58.	Felgner PL, Holm M (1989). Cationic-liposome mediated transfection. <i>Focus</i> 11:21-25.
59.	Felgner PL, Holm M, Chan H (1989). Cationic liposome mediated transfection. <i>Proc. West. Pharmacol. Soc.</i> <u>32</u> : 115-121.
60.	Berkner KL (1988). Development of adenovirus vectors for the expression of heterologous genes. <i>BioTechniques</i> <u>6</u> :616-629.
61.	DePamphilis ML, Herman SA, Martinez-Salas E, Chalifour LE, Wirak DO, Cupo DY, Miranda M (1988). Microinjecting DNA into mouse ova to study DNA replication and gene expression and to produce transgenic animals. <i>BioTechniques</i> <u>6</u> :662-680.
62.	Guild BC, Finer MH, Housman DE, Mulligan RC (1988). Development of retrovirus vectors useful for expressing genes in cultured murine embryonic cells and hematopoietic cells in vivo. <i>J Virol.</i> <u>62</u> :3795-3801.
63.	McGrory WJ, Bautista DS, Graham FL (1988). A simple technique for the rescue of early region I mutations into infectious human adenovirus type 5. <i>Virology</i> <u>163</u> (2):614-617.
64.	Waxman, S., G.B. Rossi, and T. F., The Status of Differentiation Therapy of Cancer, in The Status of Differentiation Therapy of Cancer, S. Waxman, G.B. Rossi, and T. F., Editors. 1988, Raven Press: New York, NY. P. 1-422 (Table of Contents only).
65.	Felgner PL, Gadek TR, Holm M, Roman R, Chan HW, Wenz M, Northrop JP, Ringold GM, Danielsen M (1987). Lipofection: a highly efficient, lipid-mediated DNA-transfection procedure. <i>Proc. Natl. Acad. Sci. USA</i> <u>84</u> :7413-7417.
66.	Ghosh-Choudhury G, Graham FL (1987). Stable transfer of a mouse dihydrofolate reductase gene into a deficient cell line using human adenovirus vector. <i>Biochem. Biophys. Res. Commun.</i> <u>147</u> (3):964-973.

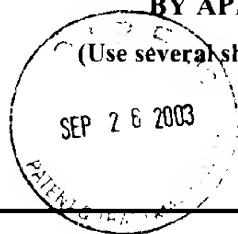
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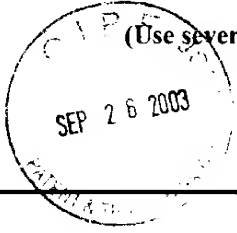
67.	Rossi P, de Crombrughe B (1987). Identification of a cell-specific transcriptional enhancer in the first intron of the mouse alpha 2 (type I) collagen gene. <i>Proc. Natl. Acad. Sci. USA</i> <u>84</u> :5590-5594.
68.	Ghosh-Choudhury G, Haj-Ahmad Y, Brinkley P, Rudy J, Graham FL (1986). Human adenovirus cloning vectors based on infectious bacterial plasmids. <i>Gene</i> <u>50</u> :161-171.
69.	Haj-Ahmad Y, Graham FL (1986). Development of a helper-independent human adenovirus vector and its use in the transfer of the herpes simplex virus thymidine kinase gene. <i>J. Virol.</i> <u>57</u> :257-274.
70.	Hock RA, Miller AD (1986). Retrovirus mediated transfer and expression of drug resistance genes in human hemopoietic progenitor cells. <i>Nature</i> <u>320</u> :275-277.
71.	Stavridis JC, Deliconstantinos G, Psallidopoulos MC, Armenakas NA, Hadjiminis DJ, Hadjiminis J (1986). Construction of trans ferrin-coated liposomes for in vivo transport of exogenous DNA to bone marrow erythroblasts in rabbits. <i>Exp. Cell Res.</i> <u>164</u> :568-572.
72.	Wigand R, Adrian T (1986). Classification and epidemiology of adenoviruses. In: <i>Adenovirus DNA</i> . Doerfler W, ed. Martinus Nijhoff Pub., Boston. pp. 408-441.
73.	Fisher PB, Prignoli DR, Herms H Jr, Weinstein IB, Pestka S (1985). Effects of combined treatment with interferon and mezerein on melanogenesis and growth in human melanoma cells. <i>J. Interferon Res.</i> <u>5</u> :11-22.
74.	Kaufman RJ (1985). Identification of the component necessary for adenovirus translational control and their utilization in cDNA expression vectors. <i>Proc. Natl. Acad. Sci. USA</i> <u>82</u> :689-693.
75.	Schmidt A, Setoyama C, de Crombrughe B (1985). Regulation of a collagen gene promoter by the product of viral mos oncogene. <i>Nature</i> <u>314</u> :286-289.
76.	Wong GG, Witek JS, Temple PA, Wilkens KM, Leary AC, Luxenberg DP, Jones SS, Brown EL, Kay RM, Orr EC, Shoemaker C, Golde DW, Kaufman RJ, Hewick RM, Wang EA, Clark SC (1985). Human GM-CSF: Molecular cloning of the complementary DNA and purification of the natural and recombinant proteins. <i>Science</i> <u>228</u> :810-815.
77.	Van Doren K, Gluzman Y (1984). Efficient transformation of human fibroblasts by adenovirus-simian virus 40 recombinants. <i>Mol. Cell. Biol.</i> <u>4</u> (8):1653-1656.

NY02:458771.1

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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(Use several sheets if necessary)	Filing Date February 29, 2000	Group 1636
	Examiner Qian, C.	RECEIVED OCT 02 2003 TECH CENTER 1600/2900

78.	Berkner KL, Sharp PA (1983). Generation of adenovirus by transfection of plasmids. <i>Nucleic Acids Res.</i> <u>11</u> (17):6003-6020.
79.	Capecchi MR, Luciw PA, Bishop JM, Varmus HE (1983). Location and function of retroviral and SV40 sequences that enhance biochemical transformation after microinjection of DNA. In: <i>Enhancer and Eukaryotic Gene Expression</i> . Gluzman Y, Shenk T, eds. Cold Spring Harbor Laboratories. pp. 101-102.
80.	Jolly DJ, Esty AC, Subramani S, Friedmann T, Verma IM (1983). Elements in the long terminal repeat of murine retroviruses enhance stable transformation by thymidine kinase gene. <i>Nucleic Acids Res.</i> <u>11</u> :1855-1872.
81.	Panicali D, Paoletti E (1983). Construction of poxvirus as cloning vectors: Insertion of the thymidine kinase gene from herpes simplex virus into the DNA of infectious vaccine virus. <i>Proc. Natl. Acad. Sci. USA</i> <u>79</u> :4927-4931.
82.	Smith GL, Mackett M, Moss B (1983). Infectious vaccinia virus recombinants that express hepatitis B virus surface antigens. <i>Nature</i> <u>302</u> :490-495.
83.	Gorman CM, Moffat LF, Howard BH (1982). Recombinant genomes which express chloramphenicol acetyltransferase in mammalian cells. <i>Mol. Cell. Biol.</i> <u>2</u> (9):1044-1051.
84.	Gluzman Y, Reichl H, Solnick D (1982). Helper-free adenovirus type-5 vectors. In: <i>Eukaryotic Viral Vectors</i> . Gluzman Y, ed. Cold Spring Harbor Laboratories. pp. 187-192.
85.	Schaefer-Ridder M, Wang Y, Hofschneider PH (1982). Liposomes as gene carriers: Efficient transduction of mouse L cells by thymidine kinase gene. <i>Science</i> <u>215</u> :166-168.
86.	Breathnach R, Chambon P (1981). Organization and expression of eucaryotic split genes coding for proteins. <i>Ann. Rev. Biochem.</i> <u>50</u> :349-383.
87.	Colbere-Garapin F, Horodniceanu F, Kourilsky P, Garapin AC (1981) A new dominant hybrid selective marker for higher eukaryotic cells. <i>J. Mol. Biol.</i> <u>150</u> :1-14.
88.	Mulligan RC, Berg P (1981). Selection for animal cells that express the <i>Escherichia coli</i> gene coding for xanthine-guanine phosphoribosyltransferase. <i>Proc. Natl. Acad. Sci. USA</i> <u>78</u> :2072-2076.

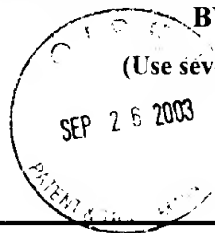
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Fisher <i>et al.</i>	
(Use several sheets if necessary)	Filing Date February 29, 2000	Group 1636
	Examiner Qian, C.	



89.	Ringold G, Dieckmann B, Lee F (1981). Co-expression and amplification of dihydrofolate reductase cDNA and the Escherichia coli XGPRT gene in Chinese hamster ovary cells. J. Mol. Appl. Genet. <u>1</u> :165-175.
90.	Sarver N, Gruss P, Law MF, Khoury G, Howley PM (1981). Bovine papilloma virus DNA: a novel eukaryotic cloning vector. Mol. Cell Biol. <u>1</u> :486-496.
91.	Corden J, Wasylyk B, Buchwalder A, Sassone-Corsi P, Kedinger C, Chambon P (1980). Promoter sequences of eukaryotic protein-coding genes. Science <u>209</u> :1406-1414.
92.	Maxam AM, Gilbert W (1980). Sequencing end-labeled DNA with base-specific chemical cleavages. Methods Enzymol. <u>65</u> :499-560.
93.	Urlaub G, Chasin LA (1980). Isolation of Chinese hamster cell mutants deficient in dihydrofolate reductase activity. Proc. Natl. Acad. Sci. USA <u>77</u> :4216-4220.
94.	Bacchetti S, Graham FL (1977). Transfer of gene for thymidine kinase-deficient human cells by purified herpes simplex viral DNA. Proc. Natl. Acad. Sci. USA <u>74</u> :1590-1594.
95.	Fowler AV, Zabin I (1977). The amino acid sequence of beta-galactosidase of Escherichia coli. Proc. Natl. Acad. Sci. USA <u>74</u> (4):1507-1510.
96.	Tu SC, Waters CA, Hastings JW (1975). Photoexcited bacterial bioluminescence. Identity and properties of the photoexcitable luciferase. Biochemistry <u>14</u> (9):1970-1974.
97.	Armelin HA (1973). Pituitary extracts and steroid hormones in the control of 3T3 cell growth. Proc. Natl. Acad. Sci. USA <u>70</u> :2702-2706.
98.	Graham FL, van der Eb AJ (1973). A new technique for the assay of infectivity of human adenovirus 5 DNA. Virology <u>52</u> :456-467.
99.	Freireich EJ, Gehan EA, Rall DP, Schmidt LH, Skipper HE (1966). Quantitative comparison of toxicity of anticancer agents in mouse, rat, hamster, dog, monkey, and man. Cancer Chemother. Rep. <u>50</u> :219-244.

NY02:458771.1

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Filing Date February 29, 2000	Group 163 RECEIVED
	Examiner Qian, C.	OCT 02 2003
TECH CENTER 1600/2000		

	100.	Waxman, S., ed. Differentiation Therapy (Ares Serono Symposia Publications, Rome). Vol. 10. 1995. pp. 1-531 (Table of Contents only).
	12	Lin JJ, Jiang H, Fisher PB (1998). Melanoma differentiation associated gene-9, mda-9, is a human gamma interferon responsive gene. <i>Gene</i> 207:105-110.
	6	Jiang H, Lin JJ, Su ZZ, Goldstein NI, Fisher PB (1995). Subtraction hybridization identifies a novel melanoma differentiation associated gene, mda-7, modulated during human melanoma differentiation, growth, and progression. <i>Oncogene</i> 11: 2477-2486.
	7	Jiang H, Lin J, Su ZZ, Herlin M, Kerbel RS, Weissman BE, Welch DR, Fisher PB (1995). The melanoma differentiation-associated gene mda-6, which encodes the cyclin-dependent kinase inhibitor p21, is differentially expressed during growth, differentiation, and progression in human melanoma cells. <i>Oncogene</i> 10:1855-1864.

NY02:458771.1

Examiner

Date Considered

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